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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,042	07/25/2003	Michael Marquant	5727-213556	4047

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EXAMINER

HYUN, PAUL SANG HWA

ART UNIT	PAPER NUMBER
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1772

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/628,042	Applicant(s) MARQUANT ET AL.	
	Examiner PAUL S. HYUN	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-8 and 11-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-8 and 11-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed by Applicant on December 6, 2010 has been acknowledged. Claims 1, 2, 4, 6-8 and 11-22 remain pending. Applicant amended claims 1, 12, 14, 15, 18 and 19.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims **1, 2, 6-8, 15, 18, 19, 21 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamos et al. (US 2002/0053523 A1) in view of Husar (US 2002/0061260 A1).

Lamos et al. disclose an electrochemical sensor comprising a base layer 500 (support layer), a top layer 508 (support layer), and a spacer 504 (transport layer) situated between the support layers 500 and 508 (see Figs. 6A-6C). The proximal end 504 of the transport layer is laterally displaced with respect to proximal ends 500/508 of adjacent support layers (see Fig. 6B). Transport layer 504 comprises two sections separated by a gap that defines a channel 506. The surface of support layer 500 that faces the transport layer comprises a working electrode 502 made from gold (see [0087]), and the surface of support layer 508 that faces the transport layer comprises counter electrodes 510 and 512 made from silver-silver chloride mixture (see [0103]). The electrodes are coated onto the support layers 500 and 508 (see [0088]). Each

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electrode terminates at a contact region (503, 511, 513) that is configured to connect to external electronics.

The invention disclosed by Lamos et al. differs from the claimed invention in that Lamos et al. do not disclose support layers arranged in a step-like manner such that electrode layers extend beyond an adjacent transport layer.

Husar discloses a microfluidic device for analyzing liquid samples (see Fig. 7). The device comprises a plurality of sensors that are stacked on top of one another so that different characteristics of a sample can be detected at the same time (see [0196]). The layers are arranged in a staggered formation so that the electrical contact 14 of each sensor is individually accessible by a sensing device. In light of the disclosure of Husar, it would have been obvious to one of ordinary skill in the art to stack a plurality of the sensors disclosed by Lamos et al. in a staggered arrangement such that the contact region of each electrode is accessible. If such modification is made, the device would have multiple measuring sites, and the utmost top support layer of the stacked sensors would be laterally displaced with respect to the utmost bottom support layer of the stacked sensors. In addition, each electrode layer would extend beyond an adjacent transport layer.

With respect to claim 2, the channels of the modified Lamos et al. device 506 would be aligned on top of one another in the direction in which the transport layers are stacked.

With respect to claim 6, the electrode layers disclosed by Lamos et al. comprise an electrode pair (i.e. measuring electrode and counter electrodes) in the area of the measuring sites, as discussed above.

With respect to claims 7 and 8, the electrode layers disclosed by Lamos et al. comprise a measuring electrode made from gold and a Ag/Gal counter electrode, as discussed above.

With respect to claim 15, channel 506 disclosed by Lamos et al. is a capillary channel (see [0104]).

With respect to claim 18, Lamos et al. disclose that each channel 506 can further comprise a vent 574 that leads to an exterior of the sensor (see [0129]). Thus, it would have been obvious to one of ordinary skill in the art to provide each layer of the modified Lamos et al. device with a vent that leads to an exterior of the device such that the vents are longitudinally spaced with respect to one another.

With respect to claim 19, it should be noted that the claimed control site is limited by the recitation of the intended use of the control site rather than what the control site actually comprises. The limitation “for checking the filling... control site” does not further limit the structure of the control site. Thus, any location of channel 506 disclosed by Lamos et al. can be construed to be the claimed control site.

With respect to claim 21, Lamos et al. disclose that the transport layer can be made from a double-sided adhesive that glues the support layers together (see [0124]).

With respect to claim 22, given that the stacked arrangement disclosed by Husar is intended to conduct multiple analyses simultaneously, it would have been obvious to

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one of ordinary skill in the art to use the modified Lamos et al. device to analyze/detect different components of a sample mixture (e.g. blood).

Claims **4 and 11-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lamos et al. in view of Husar as applied to claims 1, 2, 6-8, 15, 18, 19, 21 and 22 above, and further in view of Oloman et al. (US 4,118,305).

Neither Lamos et al. nor Husar disclose an insulating foil mask associated with the transport layer.

Oloman et al. disclose a device for conducting reactions wherein the device comprises a pair of electrodes and a porous, hydrophilic insulating material separating the two electrodes (see claim 1). The porous insulating material permits free flow of liquid between the electrodes while providing electrical insulation between the electrodes. In light of the disclosure of Oloman et al., it would have been obvious to one of ordinary skill in the art to provide a hydrophilic, porous insulating layer in the transport layer of the modified Lamos et al. device to permit flow of liquid between the electrodes while providing electrical insulation between the electrodes.

Claim **14** is rejected under 35 U.S.C. 103(a) as being unpatentable Lamos et al. in view of Husar as applied to claims 1, 2, 6-8, 15, 18, 19, 21 and 22 above, and further in view of Stapleton et al. (US 5,922,604).

Although Lamos et al. disclose that the working electrode in the channel of the sensor can comprise a reagent, neither Lamos et al. nor Husar disclose the use of dry reagents.

Stapleton et al. disclose a microfluidic device comprising reagents immobilized to the surface of the microfluidic channels wherein the reagents are dry (see lines 40-50, col. 11). In light of the disclosure of Stapleton et al., it would have been obvious to one of ordinary skill in the art to use dry reagents in the modified Lamos et al. device since dry reagents have longer shelf lives.

Claims **16 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable Lamos et al. in view of Husar as applied to claims 1, 2, 6-8, 15, 18, 19, 21 and 22 above, and further in view of Chow (US 6,167,910 B1).

Neither Lamos et al. nor Husar disclose a device comprising an application site that leads to multiple measuring sites.

Chow discloses a multi-layered electrochemical sensor (see Fig. 4 and lines 35-40, col. 11). Each layer of the sensor comprises a processing channel (411, 421, 431, 441) for subjecting a sample to various treatments. Instead of using a separate inlet port for each layer, the channels are connected to a common port 402 situated at an edge of the sensor. In light of the disclosure of Chow, it would have been obvious to one of ordinary skill in the art to provide the modified Lamos et al. device with a common port that can deliver a sample to all the layers of the modified device.

Claim **20** is rejected under 35 U.S.C. 103(a) as being unpatentable Liamos et al. in view of Husar as applied to claims 1, 2, 6-8, 15, 18, 19, 21 and 22 above, and further in view of Crismore (US 5,997,817).

Neither Liamos et al. nor Husar disclose a transparent window.

Crismore et al. disclose an electrochemical sensor comprising a capillary channel. The sensor comprises an optical window so that the user can determine whether the sensor is filled with a sample (see lines 55-65, col. 13). In light of the disclosure of Crismore et al., it would have been obvious to one of ordinary skill in the art to provide a window to the modified Liamos et al. sensor so that the user can determine whether the sample has been taken up by the channels.

Response to Arguments

Applicant's arguments with respect to the claims have been fully considered but they are not persuasive.

Applicant argues that the claims are allowable because neither Liamos et al. nor Husar disclose layers that are laterally displaced relative to one another in a step-like manner. This argument is not persuasive because Husar does disclose layers that are displaced relative to one another in a step-like manner (see Fig. 7). While the distal end 5" of each layer disclosed by Husar is aligned with corresponding distal ends of other layers, the proximal end of each layer is laterally and vertically displaced with respect to the proximal ends of other layers. If the device disclosed by Liamos et al. is modified pursuant to the teachings of Husar as detailed above in the rejection, then the modified Husar device would comprise "support layers [are] laterally displaced relative to one

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another in a step-like manner, such that the electrode layers comprise a connecting section extending beyond an adjacent transport layer”.

Applicant argues that the claims are allowable because there is no motivation to combine the teachings of Lamos et al. and Husar. Specifically, Applicant argues that the disclosure of Lamos et al. is directed to electrochemical sensors whereas the devices disclosed by Husar are not electrochemical sensors. Thus, according to Applicant, the staggered arrangement taught by Husar is not applicable to electrochemical sensors. This argument is not persuasive. While Applicant is correct in that the disclosure of Husar is not directed to electrochemical sensors, the section of the Husar reference relied upon is directed to the staggered, stacked arrangement of multiple, planar sensors for the purpose of conducting simultaneous analysis while providing access to each sensor. One of ordinary skill in the art would recognize that the arrangement disclosed by Husar is not limited to the specific application disclosed by Husar. Rather, one of ordinary skill in the art would recognize that the teaching is applicable to any sensor that requires access to the top surface at a distal/proximal end of the sensor. Moreover, given that the arrangement disclosed by Husar is intended to provide access to electrical contacts 14 disposed at the proximal end of each sensor (see [0136]), there is motivation to apply the teachings of Husar to sensors comprising electrical leads disposed at a proximal end of the sensor, such as the one disclosed by Lamos et al. (albeit the intended use of the electrical leads may be different). For the foregoing reasons, Applicant's argument that the claims are allowable because there is no motivation to combine the teachings of Lamos et al. and Husar is not persuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL S. HYUN whose telephone number is (571)272-8559. The examiner can normally be reached on Monday-Friday 10AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, In Suk Bullock can be reached on (571)-272-5954. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul S Hyun/
Examiner, Art Unit 1772

/In Suk Bullock/
Supervisory Patent Examiner, Art Unit 1772